

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA

Alexandria Division

UNITED STATES OF AMERICA

v.

HANOCH DAVID STEIN,

aka, "Albert Simmons,"

Defendant.

Criminal Nos. 1:14-cr-397-5

Hon. Anthony J. Trenga

Sentencing Date: 8/14/15

**POSITION OF THE UNITED STATES
WITH RESPECT TO SENTENCING**

Hanoch David Stein ("the Defendant") served as the first and the main "drop-shipper" for SB Medical from early 2011 through December 2014. In that role, he received packages of misbranded drugs and devices at UPS boxes he opened under false names, stored the products in his basement in unsafe conditions, and then shipped the drugs and devices to U.S. doctors and clinics, knowing that the illegal products would be injected into unsuspecting patients. In total, the defendant received, stored, and shipped over \$13 million worth of misbranded pharmaceuticals, all while ignoring warnings that his continued actions were criminal.

The presentence report correctly calculated the defendant's Total Offense Level as 26, his Criminal History Category as I, and the resulting advisory guidelines range as **63 to 78 months' imprisonment**. Because of the grave public safety risks caused by the defendant's reckless conduct and the strong need to deter the lucrative business of smuggling misbranded pharmaceuticals, the United States

recommends a sentence within the guidelines range. Additionally, the United States respectfully requests that the Court order that the defendant forfeit \$174,015.12, which reflects the salary he received from SB and TC Medical.

I. Offense of Conviction

SB Medical's mission was to smuggle non-FDA-approved prescription drugs and devices into the United States, and distribute them to U.S. doctors and clinics. SB Medical smuggled drugs into the country by shipping them from England to "drop-shippers" in the United States. The defendant was SB Medical's first and primary drop-shipper. Beginning in early 2011, the defendant used his Baltimore, Maryland home as SB Medical's main warehouse.

The purpose of using drop-shippers, such as the defendant, as middlemen between SB Medical's foreign suppliers and its American clients, was to dupe the clients into believing that SB Medical was a U.S. company. If SB Medical had shipped pharmaceuticals from abroad directly to its customers, the foreign origin of the products would have been obvious, and even customers who were complicit in the scheme demanded plausible deniability. That is why SB Medical shipped the drugs to Stein first, who was responsible for removing foreign labels and re-shipping the drugs to customers. Similarly, SB Medical instructed its clients to send payment checks to their "office" in Baltimore which, in reality, was really just Stein's UPS box. Upon receiving the checks, Stein would immediately forward them to SB Medical's real office in Toronto.

The defendant received drugs and devices from abroad under false names at four separate locations in the Baltimore area. The defendant would then consolidate and store the drugs in his basement in appealing conditions. When law enforcement executed a search warrant on the defendant's home, they found hundreds of boxes of misbranded pharmaceuticals, including several boxes of Lucenits (a drug that is injected into the eye) being kept in Stein's fridge next to a jar of mayonnaise, as well dozens of boxes of drugs that had been shoved into closets, and kept in the basement next to an empty beer bottle and a bong.

Many of drugs and devices the defendant handled were "cold-chain" products, meaning that they had to be shipped and stored at cold temperatures in order to be safe and effective. The defendant ignored this requirement, however, as the Government has confirmed through several emails. For instance, on December 12, 2011, the defendant informed defendant Tzvi Lexier and an unindicted co-conspirator that Turkish Botox had arrived warm. The unindicted co-conspirator responded: "david, please put them in the fridge - we are selling them as normal."

Over \$13 million in prescription drugs passed through the defendant's basement between 2011 and 2014. Had this matter proceeded to trial, a UPS worker was prepared to testify that he picked up roughly 13-15 boxes from the defendant's house every week. The volume of drugs and devices passing through the defendant's basement was so high that he had to hire a friend to help do the job.

The defendant continued to operate his illegal enterprise despite repeated warnings. As an initial matter, the defendant had experience working for a licensed

distributor of prescription drugs at a company called North American Dental. The defendant was thus well aware of the licensing, shipping, and storage regulations that govern the distribution of prescription drugs. Further, the defendant's UPS driver explicitly told him that it was illegal to distribute Botox without a license and asked him why he was receiving drugs under the false name "Albert Simmons." The defendant laughed. The defendant also received several warning letters from the FDA and the California Board of Pharmacy, informing him that he could not distribute prescription drugs without a license and that the products he was receiving "do not appear to comply with the law." One of these letters demanded that he "immediately cease and desist the activity of furnishing/distributing/ mailing/delivering dangerous drugs and devices." The defendant persisted.

On December 23, 2014, law enforcement executed a search warrant on the Defendant's home, recovering hundreds of boxes of misbranded pharmaceuticals. At that time, the defendant was informed that he had been indicted on charges of conspiracy, smuggling, introducing misbranded drugs and devices into interstate commerce, unlicensed wholesale distribution of prescription drugs, and conspiracy to commit money laundering. The defendant was given several opportunities to cooperate with the investigation, but did not take advantage of them. The defendant was also given an opportunity to plead guilty and accept responsibility in a timely fashion. He did not take that opportunity either.

Rather, the Defendant plead guilty on May 7, 2015, just before his scheduled trial date of May 13, 2015, to one count of conspiracy to smuggle into and distribute

within the United States misbranded prescription drugs and devices and one count of unlicensed wholesale distribution of prescription drugs. Conspiracy is punishable by a maximum of five years of imprisonment, a \$250,000 fine, three years of supervised release, and a \$100 special assessment. Unlicensed distribution of prescription drugs is punishable by a maximum of ten years of imprisonment, a \$250,000 fine, three years of supervised release, and a \$100 special assessment

II. Relative Culpability of Conspirators

Five other SB Medical employees are awaiting sentencing by this Court in addition to the defendant. For the Court's convenience, the Government has included a brief description of each defendant's role in the Conspiracy, as well as a ranking of each defendant's relative culpability, from most to least culpable.

Notably, this ranking does not take into account any cooperation credit that has been or may be recommended.

Rank	Defendant	Sentencing	Salary	Role
1	David Burke	August 21	\$1,301,626	Director of sales and leader of day-to-day operations. Trained sales team in how to mislead clients. Instructed drop-shippers on when and how to ship packages, including advising them to use false names and addresses, and to ship cold-chain products at room temperature.
2	Shlomo Rabi	August 21	\$356,901	Senior member of sales team. Recruited, trained, and supervised co-conspirators such as Ibrahimian, Murlis, and R. Rabi.
3	David Stein	August 14	\$174,015	Operated primary warehouse in Baltimore, Md. Received, stored, and shipped over \$13 million in misbranded drugs and devices. Ignored requirements for safe shipment and storage of cold-chained products.

4	Asaf Ibrahimian/ Reuven Mirlis	August 14	\$173,469 (combined)	Members of SB Medical Sales staff. Engaged in deceptive practices under the direction of Burke and Sholmo Rabi.
6	Rivka Rabi	August 7	\$54,821	Operated secondary warehouse in New Jersey. Received, stored, and shipped over \$4 million in misbranded drugs and devices.

III. Sentencing Guidelines Calculation

The defendant's Guidelines Range was properly calculated by the Probation Office as **63-78 months of imprisonment**, given a total offense level of 26 and a criminal history category of I:

Guideline	
Base Offense Level (Section 2B1.1(a)(2))	6
Loss more than \$7,000,000 and no more than \$20,000,000 (Section 2B1.1(b)(1)(K))	+20
Offense committed outside United States/ Sophisticated Means (Section 2B1.1(b)(10)(B)&(C))	+2
Acceptance of responsibility (Section 3E1.1(a))	-2
TOTAL	26

PSR ¶¶ 61-70.

IV. Application of Sentencing Factors

Although the Sentencing Guidelines are advisory, the Court is required to “consult those Guidelines and take them into account when sentencing.” *United States v. Booker*, 543 U.S. 220, 264 (2005). A “district court shall first calculate ... the range prescribed by the guidelines. Then, the court shall consider that range as well as other relevant factors set forth in the guidelines and those factors set forth

in [18 U.S.C.] § 3553(a) before imposing the sentence.” *United States v. Hughes*, 401 F.3d 540, 546 (4th Cir. 2005) (citation omitted). The § 3553(a) factors include:

- the nature and circumstances of the offense and the history and characteristics of the defendant;
- the need for the sentence imposed to reflect the seriousness of the offense, to promote respect for the law, and to provide just punishment for the offense; to afford adequate deterrence to criminal conduct; to protect the public from further crimes of the defendant; and to provide the defendant with needed educational or vocational training, medical care, or other correctional treatment in the most effective manner;
- the kinds of sentences available;
- the kinds of sentence and the sentencing range established for the applicable category of offense committed by the applicable category of defendant as set forth in the guidelines;
- any pertinent policy statement;
- the need to avoid unwarranted sentence disparities among defendants with similar records who have been found guilty of similar conduct; and
- the need to provide restitution to any victims of the offense.

Here, two of these factors are particularly relevant: (1) the nature and circumstances of the offense; and (2) the need for the sentence imposed to reflect the seriousness of the offense and afford adequate deterrence to criminal conduct.

A. Nature and Circumstances of the Offense

SB Medical’s actions, which the defendant willingly furthered, created grave risks to public safety. The drugs and devices they sold are dangerous if not handled, administered, and used correctly. That is why the drugs and devices are highly regulated by the FDA. The FDA must approve any prescription drug or device before it can be sold in the United States. Even when a prescription drug or device is approved, the FDA requires that it contain very specific labels, warnings,

and instructions in order to educate doctors about how to administer the drug or device safely and to warn patients about possible side effects. *See* 21 U.S.C. § 355(d) (mandating that the FDA approve new drug applications only if the drug is “safe for use under the conditions prescribed, recommended, or suggested ***in the proposed labeling***”) (emphasis added). Drug labeling thus serves as “[t]he centerpiece of [the FDA’s] risk management” strategy because it “communicates to health care practitioners the agency’s formal, authoritative conclusions regarding the conditions under which the product can be used safely and effectively.” 71 Fed. Reg. 3934 (2006).

SB Medical’s pharmaceuticals did not contain FDA-required labels, and therefore posed serious safety risks. *See* FDA Letter to Doctors about Risks of Purchasing Unapproved Versions of Botox and Other Medications from Foreign or Unlicensed Suppliers, <http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm330610.htm> (“Medications that are not approved by FDA may lack necessary and required labeling to assure their appropriate and safe use.”). Many were missing FDA-mandated “Black-Box Warnings,” which are required “in the labeling for medications that have special problems, particularly ones that may lead to death or serious injury.” *Id.* Many were also missing FDA-mandated “Medication Guides,” which provide information to “help patients avoid serious adverse events.” *Id.*

The public health risks created by the drugs and devices the defendant stored were compounded by the reckless steps SB Medical took to cut costs and avoid

detection by law enforcement. This includes shipping cold-chain products through circuitous routes and without dry ice to avoid detection, storing products in the messy private residences of amateur employees, mostly notably the defendant himself, and maintaining little oversight of their convoluted supply-chain. As the FDA has cautioned, such illicit distribution networks pose “a number of potential risks” to patients. *See* Senate Committee on Health, Education, Labor and Pensions, Testimony of John M. Taylor, Associate Commissioner for Regulatory Affairs, FDA (May 20, 2004) (“*Taylor Testimony*”), <http://www.fda.gov/NewsEvents/Testimony/ucm113825.htm>. These risks include receiving drugs and devices of uncertain foreign origin that may be “expired, subpotent, contaminated or counterfeit.” *Id.* These risks were surely present in this case given the conspirators’ cavalier attitude towards the shipping and storage of their products. Indeed, the Government has confirmed that a sample of purported Botox recovered from the defendant’s home was counterfeit.

Because of the actions of SB Medical and its employees, such as the defendant, thousands of patients were injected with misbranded and mishandled drugs and devices without their knowledge or consent. As the FDA has warned, “[w]hen consumers take such medications, they face risks of dangerous drug interactions and/or of suffering adverse events, some of which can be life threatening. More commonly, if the drugs are subpotent or ineffective, they may suffer complications from the illnesses that their prescriptions were intended to treat, without ever knowing the true cause.” *Taylor Testimony*. Again, these risks

appear to have come to fruition in this case, as at least one doctor complained that SB Medicals their products caused side effects in five of ten patients, necessitating emergency room visits. *See* PSR ¶ 51. And the government may never know whether patients had their illnesses prolonged, or even died, because they did not receive the full strength of the drugs or devices that the defendant received, stored, and shipped.

B. The Need for the Sentence To Reflect the Seriousness of the Offense, Promote Respect for the Law and Afford Adequate Deterrence

Unfortunately, many people are perfectly willing to do what the defendant and his co-conspirators did for a chance to make the massive profits they made. As the FDA has told Congress, the task of combating the flow of misbranded pharmaceuticals into this country is “daunting”: “Each day, thousands of individual packages containing prescription drugs are imported illegally into the U.S., simply because the sheer volume has grown to exceed the capability of FDA field personnel to properly process.” *Taylor Testimony*. As a result of smugglers like SB Medical who intentionally break up large shipments of drugs and devices into many small shipments, the system is “overwhelmed by the number of incoming packages” of unapproved pharmaceuticals, which can number in the hundreds at a single port-of-entry on a single day. *Id.*

Smuggling of misbranded pharmaceuticals into this country has boomed because the leaders of that illegal business have made a calculated choice that the rewards greatly outweigh the risk. Unlike many criminals, those engaged in the

distribution of misbranded pharmaceuticals are often sophisticated actors. The defendant and his co-conspirators went to great lengths to make their illicit business difficult to detect, investigate, and prosecute. This included locating their business outside of the United States, employing false names and addresses, and adopting convoluted shipping and banking practices. Consequently, the defendant and his co-conspirators believed that their chance of facing American law enforcement was low, and that the consequences if caught were relatively minor compared to the enormous amount of money to be made.

The money to be made from flouting FDA regulations is not going to decrease, nor will the resources that it takes to investigate and prosecute sophisticated smuggling networks like the one operated by the defendant and his co-conspirators. The only way to change the cost-benefit analysis for this crime is to impose meaningful penalties on those who are convicted. If this Court does so, there is every reason to believe that would-be smugglers will get the message. *See United States v. Martin*, 455 F.3d 1227, 1240 (11th Cir. 2006) (“Because economic and fraud-based crime are more rational, cool, and calculated than sudden crimes of passion or opportunity, these crimes are prime candidates for general deterrence.”).

Conclusion

The smuggling and distribution of misbranded pharmaceuticals conducted by unlicensed and unscrupulous entities like SB and TC Medical is a serious and widespread problem. Because these crimes are calculated and pre-meditated, their investigation and prosecution is resource-intensive and difficult. Thankfully, the

same sophistication that makes these criminals hard to catch, also makes them easy to deter. A meaningful sentence for the defendant will send a message that is likely to be heard by smugglers around the world who would otherwise be willing to endanger untold numbers of American patients and risk extradition and prosecution for the chance to make the lavish proceeds received by SB and TC Medical.

Respectfully submitted,

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Date: August 7, 2015

Certificate of Service

I hereby certify that on August 7, 2015, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which will send a notification of filing (NEF) to counsel of record for the defense.

I also certify that on August 7, 2015, I will send a true and correct copy of the foregoing by e-mail to the following:

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